

REMARKS

1/11/2005 Office Communication

Claims 32 – 41, 43, 44, 46 and 53 - 57 and 59 are presently before the Examiner. Claim 32 is herein amended to delete additional references to “precursor composition”, in order to make the body of the claim consistent with the preamble. In addition, the Examiner requested in the 1/11/2005 Office Communication that the Applicant provide detailed explanations as to why the claim amendments previously presented addressed the Examiner’s novelty and obviousness rejections from the 7/1/2004 Office Action. While the Applicant believes that the previous Response is sufficient, the Applicant herein provides detailed explanations and arguments regarding the cited references.

35 USC § 102(b) rejection of claim 32 – 35, 38 – 41, 44, 46, 53 – 59 and 60.

The Examiner has rejected claim 32 – 35, 38 – 41, 44, 46, 53 – 59 and 60 under § 102(b) as being anticipated by Okada, et al. (U.S. Pat. 5,202,352). In the examiner's view Okada, et al. teach a precursor composition that comprises different compositions, such as oils, salts of metals, wax, or synthetic or natural polymers, that include polypeptides, polysaccharides, poly-fatty acid esters, polyamino acids, polyaldehydes, polyvinyl polymers, copolymer of lactic acid and glycolic acid etc. and a biologically active compound to form emboli in the vascular system (Okada, et al., claims 10 – 12 and the description in columns 7 - 9). The examiner further opines the Okada, et al. teach the molecular weight of the polymer to be in the range of 1,000 to 100,000 and concentration to be in the 1 to 80% range (Okada, et al., columns 7 – 11). Finally, the examiner is of the opinion that the Okada, et al. teach that their composition could be administered via catheter (Okada, et al, column 11, lines 1 – 25) and different solvents.

Applicants' response

Applicants have amended the claims to recite a “system” for forming a biologically active anatomical occlusion, which renders the rejection moot.

Claim 32 recites specifically:

“A system for forming a biologically active anatomical occlusion in an anatomical cavity, comprising:

- a) a polymer-forming, or dissolved polymeric, biodegradable material;
- b) a biologically active component; and,
- c) a mechanical occlusive device;

wherein component a) is present in an amount of about 5 to 50% by weight based on the overall system; wherein said system forms a biologically active, polymeric occlusion mass when introduced into an anatomical cavity; and

wherein the polymer has a molecular weight (MW_w) of at least 10,000 and less than about 500,000.”

Okada does not teach all of the claimed elements of the present application. “Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W. L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983) (citing *Soundsciber Corp. v. United States*, 360 F.2d 954, 148 USPQ 298, 301 (Ct. Cl.), *adopted*, 149 USPQ 640 (Ct. Cl. 1966)) Further, the prior art reference must disclose each element of the claimed invention **“arranged as in the claim”**. *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)(citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)). Okada teaches a precursor composition, however Okada does not teach a system that comprises a) a polymer-forming, or dissolving polymeric, biodegradable material; b) a biologically active component; and, c) a mechanical occlusive device.... Based on this argument, Okada does not anticipate claim 32 of the present application because Okada is lacking and/or missing at least one specific feature or structural recitation found in the present application, and in claim 32. Claim 32 is therefore allowable as not being anticipated by Okada. Further, Okada does not anticipate claims 33-35, 38-41, 44, 46 and 53-59 of the present application by virtue of their dependency on claim 32. Claim 60 is herein cancelled. The examiner is respectfully requested to reconsider and withdraw the rejection.

35 U.S.C. § 103 rejection of claims 32 – 60

The Examiner has rejected claims 32 – 60 under § 103 as being unpatentable over Okada, et al. in view of Cragg, et al.¹ (U.S. Pat. No. 6,558,367 B1), Whalen, et al. (U.S. Pat. 6,531,111 B1), Cragg, et al.² (U.S. Pat. No. 6,146,373), Greff, et al. (U.S. Pat. No. 6,015,541) and Murayama, et al. (U.S. Pat. No. 5,891,192). The examiner then iterates the above purported teachings of Okada, et al. and notes that Okada, et al. do not teach a composition comprising fibronectin. The examiner then opines that the other art of record indicated above teaches embolizing compositions that comprise a precursor composition, a biocompatible solvent and a therapeutic composition. In addition the examiner is of the opinion that the cited art teaches using a catheter for delivery of the composition and that the embolizing compositions were used to deliver "therapeutic compositions comprising a therapeutic protein or a radioisotope of other agents." Further the examiner noted that Murayama, et al. teaches coating occlusion coils with adhesive proteins, such as fibronectin. The examiner then states that, in the examiner's opinion, it would have been obvious to modify the composition of Okada, et al. and prepare compositions that have different polymers or different therapeutic proteins, such as fibronectin and have a molecular weight of 10,000 – 100,000 and have 5 – 50% polymer concentration and comprise biocompatible solvents, such as ethanol or DMSO.

Applicants' response

Applicants have amended the claims to recite a "system" for forming a biologically active anatomical occlusion, which renders the rejection moot.

Claim 32 recites specifically:

"A system for forming a biologically active anatomical occlusion in an anatomical cavity, comprising:

- a) a polymer-forming, or dissolved polymeric, biodegradable material;
- b) a biologically active component; and,

c) a mechanical occlusive device;
wherein component a) is present in an amount of about 5 to 50% by weight based on the overall system; wherein said system forms a biologically active, polymeric occlusion mass when introduced into an anatomical cavity; and wherein the polymer has a molecular weight (MW_w) of at least 10,000 and less than about 500,000."

Okada does not teach to, suggest to or motivate one of ordinary skill in the art to produce a system that comprises a) a polymer-forming, or dissolving polymeric, biodegradable material; b) a biologically active component; and, c) a mechanical occlusive device.... Okada merely teaches a precursor composition that comprises several compositions, none of which teach or suggest the recitation of claim 32 in its entirety. In addition, the art cited in addition to Okada (Cragg '367 patent, Whalen '111 patent, Cragg '373 patent, Greff '541 patent and Murayama '192 patent) does not correct the deficiencies in Okada related to the disclosure of the system for forming a biologically active anatomical occlusion in an anatomical cavity. The Examiner contends that Cragg '367 and Murayama '192 discloses a catheter used to deliver "therapeutic compositions comprising a therapeutic protein or a radioisotope of other agents" or discloses coating occlusion coils with adhesive proteins, such as fibronectin, respectively. However, neither of these references teaches or discloses a system comprising a mechanical occlusive device wherein the system forms a biologically active, polymeric occlusion mass **when introduced into an anatomical cavity**. The Applicant respectfully request that the Examiner specifically cite sections of Cragg and Murayama that specifically disclose, teach or suggest a system comprising a mechanical occlusive device wherein the system forms a biologically active, polymeric occlusion mass **when introduced into an anatomical cavity** or withdraw this rejection.

Based on this argument, the cited art does not render claim 32 of the present application unpatentable because the cited art does not teach to, suggest to or motivate one of ordinary skill in the art, alone or in combination, to produce or develop a system comprising a mechanical occlusive device wherein the system forms a biologically

active, polymeric occlusion mass when introduced into an anatomical cavity. Claim 32 is therefore allowable as being patentable in view of the cited art. Further, claims 33-35, 38-41, 44, 46 and 53-59 of the present application are also allowable over the cited art by virtue of their dependency on claim 32. Claim 60 is herein cancelled. The Examiner is respectfully requested to reconsider and withdraw the rejection.

CONCLUSION

Based on the amendments to the claims provided herewith and above remarks, applicant believes that claims 32 - 41, 43, 44, 46, 53 – 55 and 59 are in condition for allowance and respectfully request that these claims be passed to issue.

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